GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2220
ANSWERED ON:06.05.2016
Drug Quality Standards
Maadam Smt. Poonamben Hematbhai

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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(a) whether the Government has taken any action to address the slew of warnings from the United States Food and Drug Administration (FDA) to leading Indian pharmaceutical companies, if so, the details thereof and the reasons therefor;

(b) whether the Government intends to put in place most stringent controls to ensure India"s pharmaceutical regulatory regime adhering to global compliance and quality standards; and

(c) if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a): USA is one of the largest importers of drugs from India and the drugs exported to USA have to comply with its regulatory requirements. Isolated cases of USFDA finding shortcomings in Indian pharmaceutical products/facilities have been reported in the recent past. Details in this regard are not maintained by this Ministry.

(b) & (c): The Central and State drug regulatory authorities take a series of steps to ensure quality, safety and efficacy of drugs. Accordingly, a number of samples of drugs are drawn for testing and inspections of manufacturing sites are carried out for ensuring adherence to Good Manufacturing, Good Laboratory, Good Storage and Good Distribution Practices. The capacity of the regulatory staff is also being enhanced through a number of programmes aimed at training